K071819

JUL 26 2007

Special 510(k) Summary:

Application Date:	July 2, 2007
Sponsor:	nContact Surgical, Inc. new address: 1001 Aviation Parkway, Suite 400, Morrisville, NC 27560 formerly at: 2880 Slater Road, Suite 103, Morrisville, NC 27560
Establishment Registration Number:	3006142617
Correspondent:	Jane Ricupero Director of Regulatory & Quality 1001 Aviation Parkway, Suite 400, Morrisville, NC 27560
Contact Numbers:	Phone: 919 466-9810 x3013 Fax: 919 466-9811 E-mail: jane@ncontact.us
Device Proprietary Name:	nContact Guided Coagulation System or VisiTrax™ Guided Coagulation System Model numbers: CSK-212; CSK-515
Device Common Name:	Electrosurgical device and accessories
Device Classification:	21 CFR 878.4400
Product Code:	GEI
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Accessory Classification: Cannula	21 CFR 878.4800 (Manual surgical instrument for general use)
Accessory Product Code: Cannula	GEA (Class I exempt)
Predicate Device	1. nContact Surgical Inc., nContact Coagulation System **(CSK)** Model numbers: CSK-100; CSK-200; CSK-500
Legally marketed unmodified device 510k number	**K063012 cleared Dec. 1/06**

Device Description:

The nContact Guided Coagulation System (VisiTrax) consists of a sterile, single-use, disposable coagulation electrode device (2cm & 5cm sizes provided) intended to be used to coagulate cardiac tissue. The flexible, cooled electrode device, with a suction stabilizer feature, transmits radiofrequency (RF) energy from an Electrosurgical Generator (non-sterile, re-useable) connected through an Instrument Cable (sterile).
The functionality of this System is the same as the cleared predicate system.

Indications for Use:

The nContact Guided Coagulation System (VisiTrax) is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy.
The indications for use of this System are the same as the cleared predicate system.

Technological Characteristics:

The modified nContact Coagulation Device has minor material changes and minor design modifications with the main technological characteristics of transmitting RF energy from an electrosurgical generator connected by an instrument cable to a coagulation electrode remaining identical to the predicate device.

Performance Data:

Performance bench tests were executed to ensure that the nContact Guided Coagulation System (VisiTrax) performed as intended and met design specifications.

Substantial Equivalence Conclusion:

This special 510(k) proposes that the material and design modifications for the nContact Guided Coagulation System (VisiTrax) may be considered substantially equivalent to the legally marketed unmodified nContact Coagulation System (previously cleared under K063012 on Dec. 1, 2006) based on the results of design verification and validation. The indications for use, principle of operation, technology, performance specifications (as re-verified through design controls), labeling and sterilization parameters are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.

We believe that the nContact Guided Coagulation System (VisiTrax) is substantially equivalent to the unmodified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

nContact Surgical, Inc.
c/o Ms. Jane Ricupero
Director, Regulatory and Quality
1001 Aviation Parkway, Sutie 400
Morrisville, NC 27560

Re: K071819
Trade/Device Name: Contact Guided Coagulation System (VisiTrax™)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II (two)
Product Code: OCL
Dated: July 2, 2007
Received: July 3, 2007

Dear Ms. Ricupero:

This letter corrects our substantially equivalent letter of July 26, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071819

Device Name: nContact Guided Coagulation System (VisiTrax™)

Indications for Use: The nContact Coagulation System (VisiTrax™) is intended for the coagulation of cardiac tissue using Radiofrequency (RF) energy.

Mark N Milliken

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071819

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)